JUL 25 2011

5. 510(k) Summary

CXI™ TriForce Peripheral Crossing Set
510(k) Summary
21 CFR 807.92

1. Submitter Information:

Applicant:	Cook Incorporated
Address:	750 Daniels Way Bloomington, IN 47404
Phone Number:	(800) 468-1379
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Contact:	Molly Busenbark, MA, RAC
Contact Address:	Cook Incorporated 750 Daniels Way Bloomington, IN 47404
Contact Phone Number:	812-339-2235 Ext. 2162
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2. Device Information:

Trade name:	CXI™ TriForce Peripheral Crossing Set
Common name:	Continuous flush catheter
Classification:	Class II
Regulation:	21 CFR 870.1210
Product Code:	KRA

3. Predicate Device:

The CXI™ TriForce Peripheral Crossing Set (hereafter referred to as the CXI™ TriForce) is substantially equivalent to the CXI™ Support Catheter, manufactured by Cook Incorporated, which is cleared under 510(k) number K072724. The CXI™ TriForce is also substantially equivalent to the FineCross™ MG Coronary Micro-Guide Catheter and the Glidesheath™, manufactured by Terumo Medical Corporation, which are cleared under 510(k) numbers K082519 and K102008, respectively.

4. Comparison to Predicate Device:

It has been demonstrated that the CXI™ TriForce is comparable to the predicate devices in terms of design, intended use, materials, fundamental technology, and principal of operation.

5. Device Description:

The CXI™ TriForce is designed to facilitate wire guide exchange, infusion, and wire guide support. Each set contains the following sterile components:

- Outer 5.0 French Flexor® introducer
- Inner 4.0 French CXI™ Support Catheter
- Peel-Away® sheath

The outer Flexor® introducer is manufactured with a stainless steel coil reinforced nylon construction which provides both flexibility and support to the sheath during use. The outer Flexor® introducer is used to support the inner CXI™ Support Catheter during a procedure. The outer Flexor® introducers are available in length measurements of 55 or 90 centimeters and can be manufactured with an angled or a straight tip. The inner CXI™ Support Catheter is manufactured with 4.0 French braided flexible kink resistant shaft materials with hydrophilic coating. The flexible shaft material is a laminated material consisting of a nylon layer, stainless steel braiding and an inner polyimide, polyurethane layer, and an innermost polytetrafluoroethylene layer. The inner CXI™ Support Catheters allow acceptance of a 0.035 inch diameter (0.89 millimeters) wire guide. The inner CXI™ Support Catheter will support a wire guide while performing percutaneous peripheral intervention. The CXI™ Support Catheters are available in length measurements of 65 or 100 centimeters and can be manufactured with an angled or a straight tip.

The tetrafluoroethylene Peel-Away® sheath is included in the set for assistance when inserting the inner CXI™ Support Catheter into the outer Flexor® introducer.

6. Intended Use:

The CXI™ TriForce is intended to be percutaneously introduced into blood vessels and support a wire guide while performing percutaneous peripheral intervention. The product is also intended for injection of radiopaque contrast media for the purpose of angiography.

7. Technological Characteristics:

The proposed CXI™ TriForce consists of a Flexor® introducer, a CXI™ Support Catheter, and a Peel-Away® sheath. The CXI™ TriForce is substantially equivalent to the CXI™ Support Catheter (K072724), the FineCross™ MG Coronary Micro-Guide Catheter (K082519), and the Glidesheath™ (K102008). No new technological aspects are being introduced with the proposed device.

The proposed CXI™ TriForce was subjected to applicable testing to assure reliable design and performance under the testing parameters.

8. Test Data:

The following tests were performed to demonstrate that the CXI™ TriForce meets applicable design and performance requirements and supports a determination of substantial equivalence. Additionally, appropriate engineering tests were also performed on aged product to ensure that the CXI™ TriForce meets the performance requirements throughout the duration of shelf life.

- Tensile Strength – Testing shows the tensile strength during proper clinical use should not fracture or rupture the introducer or catheter. In conformance with the

applicable sections of BS EN ISO 11070 and ISO 10555-1, the predetermined acceptance criteria were met.

- Liquid Leakage – Testing shows there would be no liquid leakage from the introducer, introducer valve, or catheter during proper clinical use. In conformance with the applicable sections of ISO 11070 and ISO 10555-1, the predetermined acceptance criteria were met.
- Static Burst – Testing shows the pressures reached during proper clinical use (maximum pressure at maximum flow rate) are less than the static burst pressure of the catheter, and should not fracture or rupture the catheter. The predetermined acceptance criteria were met.
- Dynamic Burst – Testing shows the pressures reached during proper clinical use (maximum pressure at maximum flow rate) are less than the dynamic burst pressure of the catheter, and should not fracture or rupture the catheter. The predetermined acceptance criteria were met.
- Flow Rate – Testing shows the pressure exerted at the maximum flow rate during proper clinical use should not fracture or rupture the catheter. The predetermined acceptance criteria were met.
- Biocompatibility – Testing shows the device is biocompatible. In conformance with the applicable sections of ISO 10993-1, the predetermined acceptance criteria were met.

In conclusion, the results of these tests provide reasonable assurance that the device is as safe and as effective as the predicate devices and supports a determination of substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Cook Incorporated
c/o Ms. Molly Busenbark
750 Daniels Way
Bloomington, IN 47404

JUL 25 2011

Re: K111263
Trade/Device Name: CXI TriForce Peripheral Crossing Set
Regulation Number: 21 CFR 870.1210
Regulation Name: Continuous Flush Catheter
Regulatory Class: Class II (two)
Product Code: KRA
Dated: July 13, 2011
Received: July 14, 2011

Dear Ms. Busenbark:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use Statement

510(k) Number (if known): K111263

Device Name: CXI™ TriForce Peripheral Crossing Set

Indications for Use:

The CXI™ TriForce Peripheral Crossing Set is intended to be percutaneously introduced into blood vessels and support a wire guide while performing percutaneous peripheral intervention. The product is also intended for injection of radiopaque contrast media for the purpose of angiography.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

(Division Sign-Off) Concurrence of CDRH, Office of Device Evaluation (ODE)
Division of Cardiovascular Devices

510(k) Number K111263